



1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 900 KAR 6:065. Certificate of need application process.

4 (Amendment)

5 RELATES TO: KRS 216B.015, 216B.040, 216B.062(1), 216B.085, 216B.095

6 STATUTORY AUTHORITY: KRS 216B.040(2)(a)1

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
9 Program and to promulgate administrative regulations as necessary for the program.
10 This administrative regulation establishes the requirements necessary for the orderly
11 administration of the certificate of need application, review, decision, and reconsidera-
12 tion process.

13 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6).

14 (2) "Certificate of Need Newsletter" means the monthly newsletter that is published
15 by the cabinet regarding certificate of need matters and is available on the Certificate of
16 Need Web site at <http://chfs.ky.gov/ohp/con>.

17 (3) "Days" means calendar days, unless otherwise specified.

18 (4) "Formal review" means the review of an application for certificate of need which
19 is reviewed within ninety (90) days from the commencement of the review as provided
20 by KRS 216B.062(1) and which is reviewed for compliance with the review criteria set
21 forth at KRS 216B.040 and 900 KAR 6:070.

1 (5) "Nonsubstantive review" is defined by KRS 216B.015(18).

2 (6) "Owner" means a person as defined in KRS 216B.015(22) who is applying for the
3 certificate of need and will become the licensee of the proposed health service or facili-
4 ty.

5 (7) "Proposed service area" means the geographic area the applicant proposes to
6 serve.

7 (8) "Secretary" is defined by KRS 216B.015(26).

8 (9) "Show cause hearing" means a hearing during which it is determined whether a
9 person or entity has violated provisions of KRS Chapter 216B.

10 Section 2. ~~[Letter of Intent. (1) Except for an applicant requesting nonsubstantive~~
11 ~~review under the provisions of KRS 216B.095(3)(a) through (f), OHP Form 1, Letter of~~
12 ~~Intent, incorporated by reference in 900 KAR 6:055, shall be filed with the cabinet by an~~
13 ~~applicant for a certificate of need.~~

14 ~~(2) Upon receipt of a letter of intent, the cabinet shall within three (3) days provide~~
15 ~~the sender with written acknowledgment of receipt of the letter and shall publish notice~~
16 ~~of the receipt in the next published Certificate of Need Newsletter.~~

17 ~~(3) An application for a certificate of need shall not be processed until the letter of~~
18 ~~intent has been on file with the cabinet for thirty (30) days.~~

19 Section 3.] Certificate of Need Application. (1) An applicant for a certificate of need
20 shall file an application with the cabinet on the appropriate certificate of need application
21 form: OHP - Form 2A, OHP - Form 2B, or OHP - Form 2C, incorporated by reference in
22 900 KAR 6:055.

23 (2) To file an application for certificate of need, the applicant shall file an original and

one (1) copy of the appropriate certificate of need application form together with the prescribed fee set forth in 900 KAR 6:020 on or before the deadlines established by 900 KAR 6:060.

(3) Formal or nonsubstantive review of an application for a certificate of need shall not begin until the application has been deemed complete by the cabinet.

(4) The cabinet shall deem an application complete if the applicant has:

(a) Provided the cabinet with all of the information necessary to complete the application; or

(b) Declined to submit the requested information and has requested that its application be reviewed as submitted.

(5) Once an application has been deemed complete, the applicant shall not submit additional information regarding the application unless the information is introduced at a public hearing.

(6) Once an application has been deemed complete, it shall not be amended to:

(a) Increase the scope of the project;

(b) Increase the amount of the capital expenditure;

(c) Expand the size of the proposed service area;

(d) Change the location of the health facility or health service; or

(e) Change the owner, unless the application involves a licensed health facility and a change of ownership with appropriate notice has occurred after the application was submitted.

(7) An application that has been deemed complete may be amended at a public hearing to:

1 (a) Decrease the scope of the project;

2 (b) Decrease the amount of the capital expenditure; or

3 (c) Decrease the proposed service area.

4 (8) An applicant which has had a certificate of need approved under the nonsub-
5 stantive review provisions of KRS 216B.095(3)(a) through (f) may request that the cabi-
6 net change the specific location to be designated on the certificate of need if:

7 (a) The facility has not yet been licensed;

8 (b) The location is within the county listed on the certificate of need application; and

9 (c) The applicant files a written request with the cabinet within 180 days of the date
10 of issuance of the certificate of need. A request shall include the reason why the change
11 is necessary.

12 ~~(9) [If an application is not filed with the cabinet within one (1) year of the date of~~
13 ~~the filing of a letter of intent, the letter of intent shall expire, and the applicant shall file a~~
14 ~~new letter of intent at least thirty (30) days prior to submitting an application.~~

15 ~~(10) If an application is withdrawn, the applicant shall file a new letter of intent at~~
16 ~~least thirty (30) days prior to resubmitting an application.~~

17 ~~(11)]~~ An application that is not deemed complete within one (1) year from the date
18 that it is filed shall expire and shall not be placed on public notice or reviewed for ap-
19 proval.

20 Section 3.4. Certificate of Need Review. (1) Prior to being reviewed for the ap-
21 proval or denial of a certificate of need, an application for certificate of need shall be re-
22 viewed for completeness pursuant to Section 5 of this administrative regulation.

23 (2) Unless granted nonsubstantive review status under the criteria in 900 KAR

1 6:075, an application for a certificate of need shall be reviewed for approval or denial
2 according to the formal review criteria set forth in 900 KAR 6:070.

3 (3) If granted nonsubstantive review status under the criteria in 900 KAR 6:075, an
4 application for a certificate of need shall be reviewed for approval or denial of the certifi-
5 cate of need according to the nonsubstantive review criteria set forth in 900 KAR 6:075.

6 Section 4.[5-] Completeness Review. (1) Fifteen (15) days after the deadline for fil-
7 ing an application in the next appropriate batching cycle, the cabinet shall conduct an
8 initial review to determine if the application is complete for formal review or nonsubstan-
9 tive review requested pursuant to KRS 216B.095(3)(a) through (f).

10 (2) If the cabinet finds that the application for formal review is complete, the cabinet
11 shall:

12 (a) Notify the applicant in writing within one (1) day that the application has been
13 deemed complete and that review of the application for the approval or denial of a certif-
14 icate of need shall begin upon public notice being given; and

15 (b) Give public notice in the next appropriate Certificate of Need Newsletter, pursu-
16 ant to the timetable set forth in 900 KAR 6:060, that review of the application for ap-
17 proval or denial of a certificate of need has begun.

18 (3) If the cabinet finds that the application for nonsubstantive review is complete, the
19 cabinet shall notify the applicant in writing within ten (10) days that the application has
20 been deemed complete and that review of the application for the approval or denial of a
21 certificate of need shall begin upon public notice being given.

22 (4) A decision to grant or deny nonsubstantive review status shall be made within ten
23 (10) days of the date the applicant is notified that the application has been deemed

1 complete.

2 (5) The cabinet shall give public notice for applications granted nonsubstantive re-
3 view status under the provisions of KRS 216B.095(3)(a) through (f) in the next appropri-
4 ate Certificate of Need Newsletter, pursuant to the timetable set forth in 900 KAR 6:060,
5 that status has been granted and that review of the application for approval or denial of
6 a certificate of need has begun.

7 (6) If the cabinet finds that the application is incomplete, the cabinet shall:

8 (a) Provide the applicant with written notice of the information necessary to com-
9 plete the application; and

10 (b) Notify the applicant that the cabinet shall not deem the application complete un-
11 less within fifteen (15) days of the date of the cabinet's request for additional infor-
12 mation:

13 1. The applicant submits the information necessary to complete the application by
14 the date specified in the request; or

15 2. The applicant requests in writing that the cabinet review its application as submit-
16 ted.

17 (7) If, upon the receipt of the additional information requested, the cabinet finds that
18 the application for formal review is complete, the cabinet shall:

19 (a) Notify the applicant in writing that:

20 1. The application for formal review has been deemed complete; and

21 2. Review of the application for the approval or denial of a certificate of need shall
22 begin upon public notice being given; and

23 (b) Give public notice in the next appropriate Certificate of Need Newsletter, pursuant

1 to the timetable set forth in 900 KAR 6:060, that review of the application for approval or
2 denial of a certificate of need has begun.

3 (8) If, upon the receipt of the additional information requested, the cabinet finds that
4 an application for nonsubstantive review is complete, the cabinet shall:

5 (a) Notify the applicant in writing that:

6 1. The application has been deemed complete;

7 2. Review of the application for the approval or denial of a certificate of need shall
8 begin upon public notice being given; and

9 3. A decision to grant or deny nonsubstantive review status shall be made within ten
10 (10) days of the date that the application was deemed complete; and

11 (b) Give public notice in the next appropriate Certificate of Need Newsletter, pursu-
12 ant to the timetable set forth in 900 KAR 6:060, for applications granted nonsubstantive
13 review status under the provisions of KRS 216B.095 (3)(a) through (f) that status has
14 been granted and that review of the application for approval or denial of a certificate of
15 need has begun.

16 (9) If the information submitted in response to the cabinet's request for additional in-
17 formation is insufficient to complete the application, the cabinet shall:

18 (a) Request the information necessary to complete the application; and

19 (b) Inform the applicant that the application shall not be deemed complete and shall
20 not be placed on public notice until:

21 1. The applicant submits the information necessary to complete the application; or

22 2. The applicant requests in writing that its application be reviewed as submitted.

23 (10) Once an application has been deemed complete, an applicant shall not submit

1 additional information to be made part of the public record unless:

2 (a) The information is introduced at a public hearing;

3 (b) For a deferred application for formal review, the additional information is submit-
4 ted at least twenty (20) days prior to the date that the deferred application is placed on
5 public notice; or

6 (c) For a deferred application for nonsubstantive review, the additional information is
7 submitted at least ten (10) days prior to the date that the deferred application is placed
8 on public notice.

9 (11) A determination that an application is complete shall:

10 (a) Indicate that the application is sufficiently complete to be reviewed for approval
11 or disapproval;

12 (b) Not be determinative of the accuracy of, or weight to be given to, the information
13 contained in the application; and

14 (c) Not imply that the application has met the review criteria for approval.

15 Section 5.~~[6.]~~ Notice of Decision. (1) The cabinet shall notify the applicant and any
16 party to the proceeding of the final action on a certificate of need application within three
17 (3) days.

18 (2) Notification of approval shall be in writing and shall include:

19 (a) Verification that the review criteria for approval have been met;

20 (b) Specification of any terms or conditions limiting a certificate of need approval, in-
21 cluding limitations regarding certain services or patients. This specification shall be
22 listed on the facility or service's certificate of need and license;

23 (c) Notice of appeal rights; and

1 (d) The amount of capital expenditure authorized, if applicable.

2 (3) Written notification of disapproval shall include:

3 (a) The reason for the disapproval; and

4 (b) Notice of appeal rights.

5 (4) An identical application for certificate of need that is disapproved shall not be re-
6 filed for a period of twelve (12) months from the original date of filing, absent a change
7 in circumstances.

8 Section 6.[7.] Deferral of an Application. (1)(a) Except as described in paragraphs
9 (b) and (c) of this subsection, an applicant may defer review of an application a maxi-
10 mum of two (2) times by notifying the cabinet in writing of its intent to defer review.

11 (b) An applicant shall not defer review of an application filed pursuant to 900 KAR
12 6:080 to alleviate an emergency circumstance.

13 (c) If an application has been deferred prior to the effective date of this administra-
14 tive regulation, an applicant may defer review of the application a maximum of one (1)
15 additional time.

16 (d)1. If the application has been granted nonsubstantive review status under the
17 provisions of KRS 216B.095(3)(a) through (f), the notice to defer shall be filed pursuant
18 to 900 KAR 6:090 no later than five (5) days prior to the date that the decision is due on
19 the application unless a hearing has been scheduled.

20 2. If a hearing has been scheduled, the notice to defer shall be filed pursuant to 900
21 KAR 6:090 no later than six (6) days prior to the date of the hearing.

22 (e)1. If the application is being reviewed under formal review, the notice to defer
23 shall be filed pursuant to 900 KAR 6:090 no later than ten (10) days prior to the date

1 that the decision is due on the application unless a hearing has been scheduled.

2 2. If a hearing has been scheduled, the notice to defer shall be filed pursuant to 900
3 KAR 6:090, no later than eight (8) days prior to the date of the hearing.

4 (f) If a hearing has been scheduled, the applicant shall also notify all parties to the
5 proceedings in writing of the applicant's intent to defer the application.

6 (2) If a notice to defer an application for formal review is filed, the application shall
7 be deferred to the next regular batching cycle and shall be placed on public notice pur-
8 suant to the timetables set forth in 900 KAR 6:060.

9 (3) If an application for formal review is deferred, an applicant may update its appli-
10 cation by providing additional information to the cabinet at least twenty (20) days prior to
11 the date that the deferred application is placed on public notice.

12 (4) If a notice to defer an application which has been granted nonsubstantive review
13 is filed, the application shall be deferred and shall be placed on public notice in the Cer-
14 tificate of Need Newsletter published the following month.

15 (5) If an application for nonsubstantive review is deferred, an applicant may update
16 its application by providing additional information to the cabinet at least ten (10) days
17 prior to the date that the deferred application is placed on public notice.

18 (6) In order for a hearing to be held on a deferred application, a hearing shall be re-
19 quested by either the applicant or an affected person within:

20 (a) Ten (10) days of the deferred application being placed on public notice if the ap-
21 plication has been granted nonsubstantive review status; or

22 (b) Fifteen (15) days of the deferred application being placed on public notice if the
23 application is being reviewed under the provision of formal review.

1 Section 7.[8-] Withdrawal of an Application. (1) An applicant may withdraw an appli-
2 cation for certificate of need by notifying the cabinet in writing of the decision to with-
3 draw the application prior to the entry of a decision to deny or approve the application.

4 (2) If a hearing has been scheduled or held on the application, the applicant shall al-
5 so notify all parties to the proceedings in writing of the applicant's decision to withdraw
6 the application.

7 (3) If an applicant withdraws a deferred application between the effective date of this
8 administrative regulation and June 30, 2015 and submits a new application for the same
9 proposed health facility or service within five (5) years from the date of withdrawal, the
10 cabinet shall apply the application fee which was submitted for the withdrawn applica-
11 tion toward the fee assessed pursuant to 900 KAR 6:020 for the new application.

12 Section 8.[9-] Location of New and Replacement Facilities. A certificate of need ap-
13 proved for the establishment of a new facility or the replacement of an existing facility
14 shall be valid only for the location stated on the certificate.

15 Section 9.[10-] Requests for Reconsideration. (1) Requests for reconsideration shall
16 be filed, pursuant to 900 KAR 6:090, within fifteen (15) days of the date of the notice of
17 the cabinet's final decision relating to:

18 (a) Approval or disapproval of an application for a certificate of need;

19 (b) An advisory opinion entered after a public hearing;

20 (c) Revocation of a certificate of need; or

21 (d) A show cause hearing conducted in accordance with 900 KAR 6:090.

22 (2) A copy of the request for reconsideration shall be served by the requester on all
23 parties to the proceedings.

1 (3) A party to the proceedings shall have seven (7) days from the date of service of
2 the request for reconsideration to file a response to the request with the cabinet.

3 (4) If a hearing was held pursuant to subsection (1)(a), (b), or (c) of this section, the
4 hearing officer that presided over the hearing shall enter a decision to grant or deny a
5 request for reconsideration within thirty (30) days of the request being filed.

6 (5) If a hearing was held pursuant to subsection (1)(d) of this section, the secretary
7 shall enter a decision to grant or deny a request for reconsideration within thirty (30)
8 days of the request being filed.

9 (6) If reconsideration is granted, the hearing shall be held by the cabinet in accord-
10 ance with the applicable provisions of 900 KAR 6:090, Section 3 or 4, within thirty (30)
11 days of the date of the decision to grant reconsideration, and a final decision shall be
12 entered by the cabinet no later than thirty (30) days following the conclusion of the hear-
13 ing.

14 (7) If reconsideration is granted on the grounds that a public hearing was not held
15 pursuant to KRS 216B.085, the applicant shall have the right to waive the reconsidera-
16 tion hearing if the deficiencies in the application can be adequately corrected by sub-
17 mission of written documentation.

900 KAR 6:065

REVIEWED:



Paul A. Coomes, Ph.D.
Executive Director
Office of Health Policy

10/1/14
Date

APPROVED:



Vickie Yates Brown Glisson
Secretary
Cabinet for Health and Family Services

10/7/14
Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on January 23, 2017 at 9:00 a.m. in Suite B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by January 13, 2017, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation through January 31, 2017. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Administrative Specialist, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, phone 502-564-7905, fax: 502-564-7573, email tricia.orme@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 900 KAR 6:065

Contact Persons: Diona Mullins, Office of Health Policy, phone (502)564-9592, email Diona.mullins@ky.gov; Tricia Orme, Office of Legal Services, phone (502) 564-7905, email Tricia.orme@ky.gov.

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

(b) The necessity of this administrative regulation: KRS 216B.040(2)(a)1 requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program. This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment deletes the requirement for submission of a letter of intent.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to simplify the certificate of need formal review process.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements necessary for the orderly administration of the certificate of need application, review, decision, and reconsideration process.

(d) How the amendment will assist in the effective administration of the statutes: Deletion of the requirement for a letter of intent improves the efficiency of the certificate of need process. Applicants will no longer be required to submit a letter of intent prior to the submission of the certificate of need application.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Annually approximately 150 certificate of need applications are submitted.

(4) Provide an analysis of how the entities identified in question (3) will be impacted

by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: No action is required. Letters of intent would no longer be required.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional cost to CON applicants to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities would no longer be required to submit letters of intent.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No cost

(b) On a continuing basis: No cost

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not directly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation: 900 KAR 6:065

Contact Persons: Diona Mullins, Office of Health Policy, phone (502) 564-9592, email Diona.mullins@ky.gov; Tricia Orme, Office of Legal Services, phone (502) 564-7905, email tricia.orme@ky.gov.

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Health care facilities owned by the state, county or city shall be permitted to file formal review applications without filing letters of intent.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. The authorizing statute is KRS 216B.040(2)(a)1.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate additional revenue for state or local government during the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs are necessary to administer this program during the first year.

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: